SPD Employee Continuing Education

Training Guides

Packaging and Package Integrity

Prepared by the SPD Advisory Group
March 2001

OUTLINE

OBJECTIVES

Upon completion of this session, participants will be able:

1. **Identify the major characteristics of wrapping materials.**

2. **List the methods to be used for sealing paper/plastic pouches.**

3. **Verbalize an understanding of the responsibilities for inspecting sterilized items.**

4. **Verbalize the potential outcomes if compromised packaging is used on patients.**

PACKAGING and PACKAGE INTEGRITY

INTRODUCTION

Packaging is a generic term that includes all types of materials designed to wrap, package and contain reusable supplies and medical devices for sterilization, storage and aseptic presentation for use. While it is widely accepted that sterilization is "event related" not "time related", VA Directive 7176 still requires the use of expiration dates to facilitate inventory control and package integrity inspections. Once the parameters of sterilization are obtained, it is imperative that the "package" containing the sterile items maintains the sterility of the contents. Choosing packaging material is as important as choosing the correct method of sterilization. The material chosen must allow for 1) effective penetration of the sterilant, 2) routine handling without tearing, 3) prevention of microbial egress and moisture penetration and 4) removal of contents without contamination, "aseptic presentation".

QUALITY STANDARDS

The sterilized package must maintain the sterility of the contents until opened or damaged. Material for packaging or wrapping supplies for sterilization must be specifically designed and manufactured for sterilization of medical devices. Packaging materials acceptable for this function include 140 thread –count muslin, paper and paper/plastic laminated; spun-bond fabric and metal or plastic containerized systems. The material must:

- withstand the physical conditions of the sterilization process (high temperature, moisture, pressure and/or vacuum of the sterilization process),
- allow for adequate air removal from the package and contents,
- allow effective penetration and direct contact of the sterilizing agent to every surface and every fiber of all contents and packaging; and
- allow adequate release and removal of the sterilizing agent at the end of the cycle.

At the completion of the sterilization cycle, materials used for packaging must provide sufficient barrier to microorganisms in order to protect the sterile contents from potential sources of contamination. Barrier efficiency is defined as resistance to dust and moisture penetration. Lint, dust and moisture are bacterial vehicles for transportation of microorganisms. In addition, materials designed for packaging sterile items must resist tearing and puncturing, must not be affected by atmospheric and humidity levels and seals must not deteriorate and come open. If accidental tearing or puncture does occur, or seals are ruptured, they must be easily visible and readily detectable to prevent the use of a packaged device whose sterility has been compromised.

TYPES OF PACKAGING

Wrappers (Woven and non-woven)

Prior to use, woven fabric (muslin) requires laundering, delinting and inspection for holes, worn spots, breaks in the fabrics and stains. Small holes and worn spots can be patched with vulcanized or thermoseal patches. They should be inspected whenever handled for cuts, tears, signs of moisture and excessive dust or debris. Woven materials must meet minimal standards, equivalent to or better than 140-count muslin. Muslin wrappers are most generally made of two-ply (two-thickness) fabric, sewn together on the edges only.

Nonwoven fabrics are single use disposable products. One of the most commonly used nonwoven fabrics is spunbond. They are made by pressure-bonding fibers together to form sheets of fabric. Although these fabrics have the flexibility of muslin, they are virtually lint free and are generally resistant to dust penetration due to the very small spaces between the fibers. They resist liquid penetration although they do provide excellent water vapor transmission. Papers are nonwoven but they lack the flexibility of the previously discussed nonwoven fabrics. They are not widely accepted products for in-house sterilization packaging.

Wrapped items are generally contained in two, sequentially wrapped layers of fabric. Packages that are wrapped must be securely fastened by pressure-sensitive indicator tape. Identification of contents and the initials of the preparer are placed on the pressure sensitive tape only, never write on the fabric.

Plastic protective overwraps (also known as sterility maintenance covers or dust covers) can be applied to sterilized packages after sterilization to protect the package from dust, moisture and other contaminates. The plastic material should be two to three mils thick. Items must be completely cooled and aerated before they are overwrapped in plastic.

Peel Pouches

Pouches made of plastic, paper or plastic/paper must be securely sealed with either heat (hermetically sealed), pressure-sensitive tape, or self-sealing adhesive. Plastic pouches differ for different types of sterilization processes. For instance, some plastics, Tyvek® for example, is intended for use in low temperature gas or plasma sterilizers only. Plastic and paper/plastic packages are better suited for use in steam or gas cycles. Pouches are available in a variety of sizes, to include gusseted (expandable) pouches. Select the appropriate size to accommodate the item without damaging the package and multiple folding. Pouches should be sized and applied properly to allow for adequate air and moisture removal. Inspect pouches to ensure they are free of defects. They should be checked whenever handled for signs of damage and consistency of the seal. Identification of the package should only be on the tape. Never write on the package (paper or plastic sides).

Doubling pouches facilitate aseptic presentation. Double pouches are prepared by placing the item (s) into one plastic or paper/plastic pouch and sealing. Then the items is placed in a slightly larger pouch and end-sealed. Paper side to paper side or plastic side to plastic side is the rule for double packaging plastic or paper/plastic pouches. Rubber bands, safety pins, paper clips, staples and other sharp items should not be used to bundle multiple sterile packages or to organize the contents within individual packages.

Rigid Containers

Rigid containers are constructed of anodized aluminum, stainless steel, high-temperature plastics or combination of these materials. A container system provides for containment of medical devices during preparation and sterilization, protection from contamination during storage and /or transport, aseptic presentation and containment of contaminated items being returned to the decontamination area. Metal containers that incorporate fabric filter systems are acceptable for steam, ethylene oxide and dry heat sterilization. Containers with vacuum closing valves can inhibit complete aeration of contents after sterilization and are not recommended for use in Ethylene Oxide (EtO) sterilizers. Containerized systems must be inspected routinely for evidence of tampering (continuity of seals), adherence of retention plates and evidence of filter placement.

> ***Manufacturers must provide documentation of tested performance qualifications and complete written instruction for use of their container system to include: 1) methods of sterilization the container is designed for, 2) methods for validating essential conditions of sterilization, testing and recommendations regarding the weight, density ad uniform distribution of the contents and 3) recommendations and precautions regarding the disassembly for cleaning and decontamination.***

Containerized packages are usually closed and sealed with tamper evident devices. These "tamper evident" devices must be designed so that they are destroyed when opened and must be incapable of "resealing" if opened.

PROCEDURES

Once the process of sterilization is accomplished, the packaging must keep the contents sterile until intentionally opened for use. Therefore, the integrity of the seal, is important to ensure sterile items are not contaminated at point of use. The load control number functions as an important inventory control mechanism to ensure proper rotation of stock and affords stock traceability.

Environmental controls, temperature and humidity, are important elements to prevent product deterioration or microbial contamination. Items that are not used within a 12-month span of time should be re-evaluated for the need to keep it sterile.

Each sterile item should be inspected by all personnel handling it: (a) when it is removed from the sterilizer; (b) placed in storage; (c) pulled for issue; and (d) just before opening in the clinical area.

Wrapped items should be inspected for signs of moisture, tears, pinholes, continuity of securing tape and excess dust or debris. Special attention should be paid to corners and the bottom of packages that have been in contact with the sterilization racks. Sterilizer racks should be routinely inspected for metal burrs that can damage packages.

Pouches should be inspected for continuity of seals (ruptured seals), signs of moisture, pin holes and tears.

Containerized systems should be inspected for the absence and/or damage of “tamper proof” devices, absence or improper placement of filters and any evidence of moisture.

If any of these conditions are found, the item/items are considered contaminated and the complete processing procedure must be repeated. Failure to perform these inspections may result in use of unsterile, contaminated items, which may increase potential for nosocomial infections and adverse patient outcomes.

POST TEST

1. Characteristics of wrapping material include all but:
   a. Allow penetration of sterilant
   b. Withstand sterilization process and handling
   c. Be moisture resistant
   d. Be able to visualize contents.

2. Items wrapped in muslin may be single (one layer) wrapped.
   True False

3. Sequential wrapping of sterilized item is intended to minimize contamination.
   True False

4. Sterile items must be inspected for package integrity at all times except
   a. Immediately after sterilization
   b. After use
   c. Before opening
   d. Whenever handled

5. Pouches must be inspected for
   a. Continuity of seals
   b. Signs of moisture
   c. Small holes and tears
   d. All of the above

6. Containerized systems must be inspected at point of use for
   a. Continuity of tamper proof devices
   b. Signs of moisture
   c. Integrity of gaskets
   d. a and b

7. Metal burrs on sterilization racks can be a source of damage to sterilized packages.
   True False

8. Dust covers (sterility maintenance covers) have a minimal thickness of
   a. 1-2 mil
   b. 3-5 mil
   c. 2-3 mil
   d. 20-30 mil

9. Rigid containers are designed to
    a. Maintain the sterility of the items
    b. Transport soiled instruments to decon
    c. Protect the instruments
    d. All of the above

10. Manufacturers must provide the following information for all rigid containers
    a. Expiration dates
    b. Validation process and sterilization parameters
    c. Detailed assembly and packaging instructions
    d. All except (a)

Packaging Integrity Training Guide
Answer Key

1. D
2. False
3. True
4. B
5. D
6. D
7. True
8. C
9. D
10. D